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Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?

By Marie Salter[*]

Abstract: The pharmaceutical industry stands at a peculiar place in the United States. It is one of the largest industries in the United States, "enjoy[ing] profit margins nearly four times that of the average Fortune 500 company." It is also a global leader, responsible for an enormous amount of research and development. Despite its size and power, the U.S. pharmaceutical industry is largely reviled, Perhaps what differentiates the U.S. pharmaceutical industry from the pharmaceutical industries of other nations is its "free market" price setting. Other nations, particularly those in the European Union, use government price controls to keep pharmaceutical prices low. One of the most popular systems of price control is reference pricing. Reference pricing is a method of controlling spending on drug reimbursement by using the price of similar or existing drugs to set "a reimbursement tariff (called reference price) for groups of drugs which are considered to be 'interchangeable.'" This Comment explores the validity of reference pricing as a method of reducing government healthcare spending, particularly in the United States, through comparison to foreign price controls.

[*] J.D., 2015, Northwestern University School of Law; B.A., 2010, Washington University in St. Louis. Many thanks to the JILB editorial staff, particularly Jon Dhanawade and Chris Langston. You were an invaluable part of the process! Thanks as well to Will Carpenter and Kara Cooper for their stellar editing. Any errors are my own.

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I. INTRODUCTION

The pharmaceutical industry stands at a peculiar place in the United States. It is one of the largest industries in the United States, "enjoy[ing] profit margins nearly four times that of the average Fortune 500 company."[1] It is also a global leader, responsible for an enormous amount of research and development. Despite its size and power, the U.S. pharmaceutical industry is largely reviled. "Big Pharma" casts a shadow over national dialogue—both the formal public dialogue through the media and the more informal dialogue which takes place across the internet.[2] Perhaps what differentiates the U.S. pharmaceutical industry from the pharmaceutical industries of other nations is its "free market" price setting. Other nations, particularly those in the European Union, use government price controls to keep pharmaceutical prices low. One of the most popular systems of price control is reference pricing. Reference pricing is a method of controlling spending on drug reimbursement by using the price of similar or existing drugs to set "a reimbursement tariff (called reference price) for groups of drugs which are considered to be 'interchangeable.'"[3]

This Comment explores the validity of reference pricing as a method of reducing government healthcare spending, particularly in the United States, through comparison to foreign price controls. Part II discusses the features of reference pricing and describes the various forms that reference pricing takes within the European Union. Part III focuses on Germany and its unique place in the European Union as a reference country, while Part IV analyzes reference pricing as it is used in France. Finally, Part V discusses the current state of healthcare and pharmaceutical industries in the United States and argues that a system of reference pricing will be effective in the United States, particularly under the Affordable Care Act.

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[1] Jerry Stanton, Comment, *Lesson for the United States From Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 154 (2000).

[2] A Google search for the much-touted phrase "big pharma" reveals a variety of sites of questionable veracity, including everything from "mommy bloggers," to a natural lifestyle website, to mass market books like the following: JACKY LAW, BIG PHARMA: HOW THE WORLD'S BIGGEST DRUG COMPANIES CONTROL ILLNESSES (2006).

[3] CHRISTINE HUTTIN, *Experiences with Reference Pricing, in* DRUGS AND MONEY — PRICES, AFFORDABILITY, AND COST CONTAINMENT 85 (C.P. de Joncheere et al. eds., 7th ed. 2003), *available at* http://apps.who.int/medicinedocs/pdf/s4912e/s4912e.pdfhttp://apps.who.int/medicinedocs/en/d/Js4912e/3.3.html#Js4912e.3.3.

II. REFERENCE PRICING DEFINED

Many countries use reference pricing as a method for pricing pharmaceuticals for government reimbursement.[4] Reference pricing is usually enacted through a healthcare reform law, and then put into action through specially created government committees or already existing public health committees.[5] Under reference pricing, interchangeable medicines[6] are divided into groups.[7] The prices of these drugs are then compared to the prices for the same drugs in select international markets and set accordingly.[8] Which countries are used for comparison is either specified in the originating law or determined by a government agency.[9]

After reference prices are set, if a pharmaceutical company continues to price their medication beyond the reference point, the consumer must pay the additional cost beyond the reference price.[10] Typically, neither a consumer's insurance nor the government payor system pays the difference, though some private insurance plans or "luxury" additional insurance plans do cover higher cost drugs.[11] These systems are utilized in virtually every developed nation outside of the United States.[12]

Though some countries utilize reference pricing as an informal benchmark, many have codified reference pricing in their regulatory

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[4] Lana Kraus, Note, *Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry*, 37 VAND. J. TRANSNAT'L L. 527, 529 (2004). The terms "reference pricing" and "international reference pricing" are used interchangeably throughout this Note—merely reflecting the U.S.-based perspective of the analysis—because the United States does not currently use a system of reference pricing.

[5] *Reference Prices and How They Are Set*, GEMEINSAMER BUNDESAUSSCHUSS (Feb. 9, 2014), http://www.english.g-ba.de/special-topics/pharmaceuticals/reference/; Kraus, *supra* note 4, at 536.

[6] Interchangeable medicines are typically biosimilars or bioequivalents. For an explanation of how these are defined, see subpart II(A).

[7] Pieter Dylst et al., *Reference Pricing Systems in Europe: Characteristics and Consequences*, 1 GABI J. 127, 128 (2012).

[8] The exact calculations in arriving at this number depend on what a given government chooses to base their reference pricing on. Some calculation systems, which will be discussed hereinafter, include but are not limited to the following: average price of medicines, average price of generic medicines, lowest-priced generic, and more complex systems which balance weighted averages or take into account a larger number of low-priced generics. *See* Dylst, *supra* note 7.

[9] For a more detailed discussion of how these countries are chosen, see subpart II(A).

[10] *See* Lisa Brandt, *Price Tagging the Priceless: International Reference Pricing for Medicines in Theory and Practice*, EUROPEAN CENTRE FOR INTERNATIONAL POLITICAL ECONOMY, at 2 (2013), *available at* http://www.ecipe.org/app/uploads/2014/12/ECIPE_Policy_Brief_IRP_30_May_FINAL_pdf.pdf; PHARMACEUTICAL BENEFITS BOARD, THE SWEDISH PHARMACEUTICAL REIMBURSEMENT SYSTEM - A BRIEF OVERVIEW 8 (2007) [hereinafter TLV], *available at* http://www.tlv.se/Upload/English/ENG-swe-pharma-reimbursement-system.pdf.

[11] *See* sources cited *supra* note 10.

[12] Brandt, *supra* note 10; Stanton, *supra* note 1.

systems.[13] However, these systems are not regulated by any international body. Instead, international reference pricing is governed and defined by each country that elects to utilize such a system. In general, countries which institute reference-pricing systems have some semblance of "socialized medicine."[14] Additionally, almost all reference-pricing countries base their pricing models largely on countries with low pharmaceutical prices.[15] However, because there is no governing body managing the prices governments set for pharmaceuticals, each government utilizing reference pricing has a great deal of discretion in setting prices and negotiating with pharmaceutical companies. This can result in a large disparity in pharmaceutical prices between different countries, at times seemingly at odds with the per capita income of these countries, leading to poorer countries paying high prices for pharmaceuticals.[16]

A. How Reference Groups are Defined

Reference groups are established based on three basic identifiers either alone or in combination. These identifiers are the following: active substance or ingredient, pharmacological class, and therapeutic class.

Active ingredient is defined by the World Health Organization (WHO) as "'[a]ny substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.'"[17]

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[13] *See generally* U.S. DEP'T OF COMMERCE, INT'L TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION [hereinafter ITA], *available at* http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf.

[14] Socialized medicine, however, is generally a term only used by the U.S. media.

[15] Although they are not included in this comparison, this particular feature of International Reference Pricing may have an extremely detrimental effect on developing nations. Drug developers have historically offered lower-price drugs to developing nations, particularly in instances of outbreak or pervasive disease, as well as diseases which develop due to lack of clean food and water which are common in developing nations. When developed nations craft reference prices, they often bundle these lower-priced drugs into their averages. As a result, drug developers' profits suffer because the reimbursement price is lowered in developed nations, which make up the majority of their profit margins. Perhaps as a result of this, drug companies have displayed reluctance to provide low-cost drugs to developing nations. *See* Patricia Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 185 (2003).

[16] These differences are often held as the reason behind the thriving black or grey markets in international pharmaceuticals, notably, between the United States and Canada. *See* Paula Tironi, Article, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 351 (2010).

[17] World Health Organization, *Definition of Active Pharmaceutical Ingredient* (World Health Org.,

Generic drugs are bioequivalents of name brand drugs, meaning that the active ingredient is functionally or literally the same and is delivered in a similar dosage. Beyond these active ingredients, generics can differ in their fillers, colorants, binding agents, and other elements.[18]

Reference groupings based on active ingredient does not take such nonactive differences between generic and name brand drugs into account while creating medication groups. Such a system may encourage the manufacture of biosimilars, or medications which have a similar therapeutic effect but are based on a different active ingredient. These medications would be classified in different reference groups and would be priced differently.[19] A biosimilar without a generic substitute, for example, would fare well in a system which allowed it to be priced independently of a medicine with a similar effect but many generic versions.[20] Countries which define reference groups based on active ingredient include Belgium, Finland, France, and Hungary.[21] This method is the most popular method of defining reference groups.[22]

Another method of crafting reference groups is by pharmacological class. "[A] pharmacologic class is a group of drugs that share scientifically documented properties."[23] These documented properties might include the mechanism of action (the effect of the drug "at the receptor, membrane, or tissue level"), physiologic effect "at the organ, system, or whole body level," or the chemical structure of the drug.[24] In the United States, the Food

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Working Document QAS/11.426/Rev.1, 2011), *available at* http://www.who.int/medicines/areas/quality_safety/quality_ assurance/DefinitionAPI-QAS11-426Rev1-08082011.pdf.

[18] *See* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD DRUG L.J. 417 (2011); Adam R. Young, Note, *Generic Pharmaceutical Regulation in the United States with Comparison to Europe: Innovation and Competition*, 8 WASH. U. GLOBAL STUD. L. REV. 165 (2009).

[19] *See* Kraus, *supra* note 4.

[20] This is similar to a common occurrence in the United States where pharmaceutical companies fight to maintain a market share upon the expiration of their patent. Pharmaceutical companies will often develop a similar product that is functionally altered enough to warrant a new patent—for example, an extended-release version of a medicine which has the same overall effect. These incremental changes are used to "evergreen" the company's patent protection. When patients are prescribed this new version of the medication, a generic version does not exist to be substituted. *See generally* Steven Johnson, *Innovation: It Isn't a Matter of Left or Right*, N.Y. TIMES (Oct. 30, 2010), http://www.nytimes.com/2010/10/31/business/31every.html?pagewanted=all; Jonathan Cohn, *Creative Destruction*, NEW REPUBLIC (Nov. 12, 2007), http://www.newrepublic.com/article/politics/creative-destruction.

[21] Dylst et al., *supra* note 7.

[22] *Id.*

[23] U.S. DEP'T OF HEALTH AND HUMAN SERV. ET AL., GUIDANCE FOR INDUSTRY AND REVIEW STAFF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS — DETERMINING ESTABLISHED PHARMACOLOGIC CLASS FOR USE IN THE HIGHLIGHTS OF PRESCRIBING INFORMATION, at 3 (Oct. 2009).

[24] *Id.*

and Drug Administration (FDA) has established pharmacological classes based on these factors. Upon development, drugs can be classified into an existing pharmacological class if they fit within the criteria. The FDA has also established a practice for establishing new pharmacologic classes (though pharmacological classes are not then used for reference pricing in the United States).[25] Developed foreign nations have enacted similar government processes.[26] Pharmacologic classification, as well as therapeutic class—the classification of a drug based on the condition or disease it treats, rather than the more specific biological effect encompassed under pharmacologic class[27]—can lead to a wider variety of medications being contained within a certain reference price group. Grouping by pharmacologic or therapeutic class can be a more effective price control because it allows the price regulations to contain a larger span of medications within a single price group. However, grouping by pharmacologic or therapeutic class may also lead to undesirable patient outcomes as doctors are incentivized to choose medicines based on financial reasons rather than medical reasons.[28]

B. How Reference Prices are Crafted

Once drug classes are determined, individual drugs' reference prices are generally calculated "as a function of market prices of medicines."[29] However, which medicines that are taken into account in considering the market price varies widely among different countries within and outside of the European Union. Croatia and Hungary, for example, set reference prices based on the average price of all medicines within a group. Other methods include setting prices by the lowest price in a group, pricing based on the generic drug market, and pricing by lowest price overall.

By far, the most popular method is to set the reference price for a designated group of drugs—often separated by class—based on other countries' lowest priced medicines within that designated group's reference points. Bulgaria, the Czech Republic, Finland, Italy, Poland, Spain, and Turkey use this method alone or in addition to other methods.[30] While

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[25] *Id.* at 6.

[26] *See generally* Drummond et al., *Reimbursement of Pharmaceuticals: Reference Pricing Versus Health Technology Assessment*, 12 EUR. J. HEALTH ECON. 263 (2011); Kraus, *supra* note 4.

[27] Kraus, *supra* note 4. The difference between pharmacologic and therapeutic classification is subtle but important. Pharmacological class is grouped solely by the drug's effects on the body, while therapeutic class focuses on the particular disease or condition the drug is intended to treat. These groups often overlap, but can also diverge strongly.

[28] Danzon, *supra* note 15; Stephen A. Talmadge, *Influencing Physicians' Prescribing Behavior: Ethical Issues Related to Pharmaceutical Gifts*, 11 MICH. ST. U. J. MED. & L. 303, 311 (2008).

[29] Talmadge, *supra* note 28.

[30] *Id.*

lower priced medicines often include generic medicines simply because generic medications are priced on a different scale by companies (which usually do not need to account for research and development in pricing generics), this method does not focus specifically on generic medicines in assigning prices and often includes competitively priced name brand drugs.[31]

Pricing by lowest price overall, however, may undermine the development of generic drug markets in countries where lowest price is used without special attention to generics. The generic market depends on competitive prices to sustain itself because generic manufacturers are not, for the most part, companies that also develop new drugs for the market. A system based on lowest price urges developers of name brand drugs to compete on price with generics because they can no longer be guaranteed a premium for their product.[32] This is undesirable to originators as well because they spend millions on research and development and rely on higher prices to recoup these costs.

Some nations, which place more importance on a national market for generic medicines, have based their reference prices directly on generic medicines alone. In France, reference prices are set by looking to the average price of generic medicines within a designated group or class in chosen reference countries, while Denmark and Latvia use a similar system based on the lowest priced generic medicine.[33] Countries which base reference prices on generics generally intend reference pricing to serve in part as a mechanism to grow the market of generic pharmaceuticals. Continuing decreases in price are obviously a positive result for government payors and consumers in terms of cost, but can result in a pricing "race to the bottom" that places insurmountable strain on pharmaceutical manufacturers.[34]

C. Effect of Reference Pricing on Foreign Governments and Pharmaceutical Companies

Foreign governments, particularly in the European Union, are increasingly looking to regulate healthcare across the board. As populations age, medical treatments become more sophisticated and healthcare costs rise. Reference pricing is an effective way for government payors to limit what they spend on pharmaceuticals. In the United States, a country which

[31] For a discussion of generic pricing models, see *Generic Drugs Don't Necessarily Mean Low Prices,* PBS NEWS HOUR, (Nov. 2, 2013, 12:00 AM), http://www.pbs.org/newshour/bb/health/july-dec13/costlygenrics_11-02.html.

[32] Young, *supra* note 18, at 183.

[33] *Id.* at 182 n.98.

[34] *Id.*

allows pharmaceutical companies near unbridled discretion in setting prices, the government spends approximately 8%–10% of its total health care costs on pharmaceuticals.[35] In most other countries, reference pricing has been an effective method of cost saving and could be equally effective in the United States.

Poland, for example, had a remarkably underfunded and inefficient healthcare system in the past, spending 0.63% of its Gross Domestic Product (GDP) on pharmaceutical reimbursements and 7% on health care overall. At the same time, Poland's medical industry delivered a poor level of care (for example, Poland demonstrated the lowest level of access to cancer treatment in the EU).[36] However, in 2012, Poland implemented health care reforms which, among other improvements, refined the system of reference pricing and applied more stringent caps on pharmaceutical reimbursements. In the same year, Poland saw, for the first time, a decrease in prescription reimbursement costs.[37] This decrease in costs did not further reduce quality of care, and Poland has since realized steady improvements in quality of care.[38]

Canada has also experienced great success through reference pricing. In the early 1990s, Canada began reforming their drug patent and pricing system in response to the North American Free Trade Agreement (NAFTA).[39] Canada established the Patented Medicines Price Review Board (PMPRB), which compares drug prices in Canada to foreign prices for the same drug or a similar compound. For innovative medicines, prices are compared to nine other countries. For similar compounds (generics), prices are set closely to preexisting drugs internally. Since the creation of the PMPRB, drug prices have been consistently below the Canadian consumer price index.[40]

Other countries, however, have used reference pricing as a method of controlling pharmaceutical spending in the past and subsequently abandoned it. Between 1993 and 2003, Sweden used a form of international

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[35] Stanton, *supra* note 1.

[36] Joanna Lis, President of Polish Int'l Society for Pharmacoeconomics and Outcomes Research (ISPOR) Chapter, Address at ISPOR 18th Annual Meeting: Pricing of Pharmaceuticals in Emerging Countries of the Central & Eastern European Region: The Case of POLAND 2 (May 21, 2013), *available at* http://www.ispor.org/meetings/neworleans0513/releasedpresentations/FORUM-2-Central_Eastern_Europe_Lis.pdf.

[37] *Id.*

[38] *Id.*

[39] This reform was largely because Canada's patent protections included compulsory licensing provisions that did not conform to NAFTA. NAFTA eliminated all compulsory licensing with a few exceptions. In anticipation of this change, Canada passed a law commonly known as C-91, which updated their patent laws to conform with NAFTA. Though controversial, C-91 was renewed in 1997. Stanton, *supra* note 1, at 160.

[40] Stanton, *supra* note 1, at 161.

reference pricing based on chemical equivalency and active ingredients.[41] In 2003, however, Sweden replaced this system with a drug substitution scheme. The Swedish Pharmaceutical Benefits Board cited three reasons for the change. First, the cost of reimbursed drugs was increasing. Second, Sweden's reimbursement system was overly generous. Finally, the Board was concerned about value received for spending.[42] Under the drug substation scheme system, pharmacies select the appropriate lowest priced drug.[43] Sweden now uses a government board, the Dental and Pharmaceutical Benefits Agency (TLV), to decide on reimbursement levels for new drugs. The TLV does not use reference pricing to establish reimbursement levels. Rather, it uses a product-oriented system[44] that allows for more flexibility than strict reference pricing in reimbursement and a generic substitution scheme similar to that used by insurance policies in the United States.[45] Generic substitution is mandatory in Sweden. If a patient chooses to reject a generic drug, they must pay the difference for the name brand.[46]

Reference pricing has an impact beyond the particular country imposing regulations because of the relatively small market share of foreign pharmaceutical companies in comparison to powerhouse pharmaceutical companies within the United States. In 2012, pharmaceutical research and development expenditures in the United States topped $36,810 million, while all European countries combined spent an estimated €30,000 million (roughly $40.5 million). Similarly, European countries developed fifty-five new chemical or biological entities from 2008 to 2012, while the United States developed sixty-five (Japan, a distant third, produced twenty-six, while all other nations produced sixteen).[47] Still, any analyses of price impacts on pharmaceutical companies must take into account both foreign and U.S. developers who distribute to foreign markets.

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[41] Drummond, *supra* note 26.

[42] TLV, *supra* note 10, at 2.

[43] Many states in the United States have adopted a similar system through generic substitution laws. Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. PHARM. (GENERIC DRUG REVIEW) 30 (2008).

[44] TLV clarifies that a product-oriented system means "that medicines are either granted reimbursement status for the whole of its approved area of use or not at all." TLV, *supra* note 10, at 4.

[45] Danzon, *supra* note 15, at 13.

[46] TLV, *supra* note 10, at 4.

[47] This number represents a gradual change from decades past. From 1993 to 1997, Europe led development with ninety new chemical and biological entities compared to the United States' sixty-six and Japan's sixty. Europe's numbers gradually decreased and were eclipsed by the United States from 1998 to 2002. These numbers have improved since 2007, but still demonstrate a disparity in production, especially in light of the fact that Europe is considered as a whole, while the United States represents a single country. ECORYS RESEARCH AND CONSULTING, COMPETITIVENESS OF THE EU MARKET AND INDUSTRY FOR PHARMACEUTICALS — VOLUME I: WELFARE IMPLICATIONS OF REGULATION (2009), *available at* http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_1_welfare_implications_of_regulation_en.pdf.

Regardless of the production disparity between the United States and Europe, European pharmaceutical companies expressed concern as a growing number of governments began regulating pharmaceutical pricing. Industry members feared "the growing practice by government health agencies to agree or set medicine prices by reference to other countries' prices," and predicted that the lowest-common-denominator principle would result in an overall lowering of profit margins throughout the industry.[48] These fears were perhaps justified, if not at the disastrous level indicated. In 2003, a study of Organization for Economic Cooperation and Development (OECD) countries based on U.S. Department of Commerce calculations compared estimated revenues for a group of patented drugs based on unregulated markets with actual profits from this set of drugs in various countries with extensive price regulations.[49] Among the countries studied were France, Germany, Switzerland, and the UK.[50] Each of these counties uses price controls of some sort, with Germany and France giving the most weight to reference prices within their pricing methodologies. In France, estimated revenues for reference-priced patented drugs were $5.3 billion,[51] while actual revenues were $3.8 billion. Similarly, estimated revenues in Germany were $4.7 billion, while actual revenues were $3.5 billion.[52]

These revenue differences and the anticipation of falling revenues can have a direct effect on the behavior of pharmaceutical companies in four ways. First, it may influence where companies initially choose to release and market drugs.[53] It is in a pharmaceutical company's best interest to originate a drug in a country where they are free to set the price according to their own pricing models—allowing them to potentially recoup research and development costs that are not taken into account when setting reference prices. Understandably, these countries might be less receptive to high prices if a drug has already launched at a lower price in other countries.[54]

Second, companies will attempt to ensure higher prices in other countries through gaming reference lists. Originating drugs in countries

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[48] *Pharma "is Losing Control of Pricing, and Must Present a United Case Now:" KPMG*, PHARMALETTER (June 17, 2002) [hereinafter Pharmaletter], *available at* http://www.thepharmaletter.com/article/pharma-is-losing-control-of-pricing-and-must-present-a-united-case-now-kpmg.

[49] *See* ITA, *supra* note 13, at fig. 5.

[50] *See id.*

[51] Using U.S. Dollars as the standard currency unit.

[52] ITA, *supra* note 13, at fig. 5.

[53] Drummond et al., *supra* note 26.

[54] Peter J. Rankin et al., *Global Pricing Strategies for Pharmaceutical Product Launches*, *in* THE PHARMACEUTICAL PRICING COMPENDIUM 5 (2003), *available at* http://www.crai.com/sites/default/files/publications/Global-Pricing-Strategies-for-Pharmaceutical-Product-Launches.pdf.

without pricing regulations creates a higher reference point for pricing when the drug is launched in countries that consider the "first-launch" country as a reference point in their analysis.[55] While countries generally seek lower priced reference points rather than highly priced, first-launch prices, pharmaceutical companies working in referenced-priced systems attempt to force pricing lists as high as possible.[56]

Third, beyond the ability to set their own prices, pharmaceutical companies give preference to countries that allow them to negotiate a pricing and reimbursement scheme before marketing authorization is granted, which allows them to gain a clearer picture of the gains of the marketplace before taking substantive steps towards launching the drug.[57]

Finally, reference-pricing systems may also have an effect on research and development in European markets because these costs are less likely to be recouped. According to a 2009 study by independent consultants analyzing the European pharmaceutical market, price regulations "will lower a firm's expected returns to R&D and reduce the demand for R&D investments."[58] However, this is not based on direct numbers, but on a projection study based on research and development in the United States.[59] While the potential effect of reference pricing on research and development in the U.S. pharmaceutical industry will be discussed in Part IV, it is difficult to assign reference pricing as causation rather than correlation in relation to European research and development decreases.

III. FRANCE & GERMANY

Germany, a major pharmaceutical market in the European Union, does not use a strict reference pricing system. However, Germany was one of the first countries to utilize reference pricing and was often looked to by other countries in setting their pharmaceutical prices.[60] Because of this, price changes in Germany have the potential to create wide ripple effects beyond Germany itself.

Germany requires health coverage for all citizens. In turn, 90% of

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[55] *Id.*

[56] *Id.* at 52; Drummond et al., *supra* note 26.

[57] KAI RUGGERI & ELLEN NOLTE, RAND CORP., PHARMACEUTICAL PRICING: THE USE OF EXTERNAL REFERENCE PRICING (2013), *available at* http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR240/RAND_RR240.pdf.; Patricia M. Danzon & Jonathan D. Ketcham, *Reference Pricing of Pharmaceuticals for Medicare: Evidence from Germany, The Netherlands and New Zealand* (Nat'l Bureau of Econ. Research, Working Paper No. 10007, 2004); Dylst et al., *supra* note 7.

[58] RUGGERI & NOLTE, *supra* note 57.

[59] *Id.*

[60] Danzon, *supra* note 15.

German citizens are covered by federal statutory health insurance (SHI).[61] The German healthcare system is regulated "within the Social Code Book V (Sozialgesetzbuch), which sets out the overall framework for the statutory health insurance system . . . , including coverage and reimbursement of medicines under the statutory system."[62] Article 78 of the Pharmaceutical Act, passed in 1976, regulates prescription medication safety and states that the Ministry of Economics and Technology must supervise the pharmaceutical pricing.[63]

Manufacturers primarily drive German pharmaceutical prices.[64] Highly innovative drugs in particular are not subject to reference prices, and manufacturers can set prices at will. However, a complex system of regulations and internal referencing influence reimbursement rates for SHI. Manufacturers are required to provide rebates to SHI funds, which differ depending on whether the drug in question is a patented innovative drug or an off-patent, generic drug.[65] Additionally, hospitals may negotiate rebates for inpatient drugs, and manufacturers may negotiate with retailers for discounts or rebates.[66] In short, the German pharmaceutical market is more regulated than it appears on its face.

In 2007, Germany instituted healthcare reform.[67] In November 2010, the Act on the Reform of the Market for Medicinal Products (ANM) was passed which stipulated that "from 2011 all newly licensed medicines are subject to a ('early') benefit assessment; this assessment forms the basis for determining the price of the new product."[68] Manufacturers must submit a dossier to the Federal Joint Committee supporting the benefit of the drug, and indicating that the drug is recently licensed for use or for a new therapeutic indication. The Committee then releases a report describing, among other things, "requirements for appropriate use and costs."[69] The report is used as the basis for pricing the product.

France, another country which utilizes price limits, uses various factors to set price limits, including reference prices. France also considers therapeutic merit and the economic contribution of the drug.[70] Beyond these overarching factors, France looks at particular drugs to consider what proportion of the overall national drug expenditure they make up. If a

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[61] *Id.* at 41.

[62] *Id.*

[63] *Id.*; Dylst et al., *supra* note 7.

[64] RUGGERI & NOLTE, *supra* note 57, at 41.

[65] *Id.* at 42.

[66] *Id.*

[67] *Id.*; Dylst et al., *supra* note 7.

[68] RUGGERI & NOLTE, *supra* note 57, at 43.

[69] *Id*.

[70] *Id.* at 39.

particular drug is a large portion of national expenditures, a cap is applied on what the government will pay for that particular drug.[71] This system of capping frequently prescribed drugs may be very useful in the United States. In particular, this would be useful in relation to drugs that treat diseases that are growing more common in the United States, such as diabetes and other obesity related illnesses.

IV. REFERENCE PRICING WOULD BE AN EFFECTIVE SYSTEM IN THE U.S.

International Reference pricing is increasingly common and has proven effective in foreign markets, especially in Europe.[72] However, it is not currently used in the U.S. Now, as U.S. healthcare reform is a popular topic, the opportunity exists to bundle pharmaceutical pricing reform into other healthcare reforms just as other countries have introduced reference pricing through healthcare reform.[73] Part IV considers the application of reference pricing to the U.S. pharmaceutical market. Subpart A describes the current system of pricing in the U.S. and the restrictions placed on the pharmaceutical industry, particularly through patent law. It also describes regulated pricing already in effect—Medicare, Medicaid, and specialized pricing for veteran services. Subpart B considers the impact of a pricing change on the pharmaceutical industry, while subpart C analyzes the potential effects such a change could have on patients and providers. Subpart D looks to the recently enacted Affordable Care Act and how a reference-pricing system would be affected by the Act.

A. The Current State of Pharmaceutical Pricing in the United States

The United States is the only developed nation that does not use some sort of government regulation to control pharmaceutical pricing.[74] The U.S. government, like other developed nations, regulates the health and safety of its citizens.[75] Part of this regulation includes the distribution and manufacture of pharmaceuticals,[76] much of which is executed under the Federal Food, Drug, and Cosmetic Act (FFDCA).[77] Under the FFDCA, the government interacts directly with pharmaceutical manufacturers by collecting fees and regulating the process of releasing drugs to the market,

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[71] Stanton, *supra* note 1, at 162.

[72] *See generally* Huttin, *supra* note 3; Stanton, *supra* note 1; Dylst et al., *supra* note 7.

[73] For examples, see generally Stanton, *supra* note 1.

[74] *See generally* Kraus, *supra* note 4.

[75] *See* Young, *supra* note 18, at 169–71.

[76] *Id.*

[77] *Id.* at 168.

as well as evaluating the safety of those drugs for consumers.[78] Through the FFDCA, manufacturers must complete and file "new drug applications." These applications must include extensive reports detailing "the safety and effectiveness of the drug; a full statement of the composition of the drug; a full description of the methods, facilities, and controls used at all levels of production; samples of the drug; and specimens of the labeling that may be used for the drug."[79]

Despite these regulations, the United States differs from other developed nations in that manufacturers usually set pharmaceutical pricing. Pharmaceutical innovators—manufacturers that research and develop new drugs—obtain FDA approval and patent protection as the drug moves through several testing phases.[80] At this point, patent protection allows originators to charge monopoly prices for the duration of the patent.[81] Companies balance a variety of factors to set drug prices. The most obvious of these is research and development expenditure because companies seek to recoup their investment. However, since drug prices are largely inelastic (increasing the price does not decrease the demand), companies also take into account how much insurers and patients will value the drug, the current marketplace, and a variety of other factors.[82]

Nevertheless, some price-control mechanisms do exist. Such mechanisms include government actions which affect the entire pharmaceutical industry, like the Hatch–Waxman Act, a bill which encourages generic production by expediting the process of generic drug approval.[83] However, the United States has also engaged in more limited price setting through programs like Medicare, Medicaid, and the Department of Veterans Affairs insurance plans. These smaller price controls more closely resemble the price controls used in other developed nations, and use reference pricing in various ways to create price limits.

1. The Hatch–Waxman Act

Traditionally, the U.S. patent system has protected drug originators

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[78] *Id*.

[79] Vaishali V. Shah, Note, *Prescription Drugs in America: The Pain of Pricing has an Unpromising Cure*, 2006 U. ILL. L. REV 859, 861 (2006).

[80] Seth D. Knocke, *Incentivizing Innovation: Pharmaceutical Pricing in the United States and the United Kingdom*, 20 ANNALS HEALTH L. ADVANCE DIRECTIVE 177, 179 (2011).

[81] Tironi, *supra* note 16, at 323.

[82] *See* Barry Werth, *A Tale of Two Drugs*, MIT TECH. REV. (Oct. 22, 2013), http://www.technologyreview.com/featuredstory/520441/a-tale-of-two-drugs/ (describing French drug maker Sanofi's fatal misstep in overpricing drug Zaltrap when a near equivalent drug already existed at a much lower price).

[83] *See, e.g.*, D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107 (2011).

from losing a large market share to bioequivalent competitors who release equivalent drugs and capture market share by offering lower prices.[84] The U.S. patent system originates from Article 1 of the Constitution, which states that Congress shall have the power "to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[85] Patent protections encourage development by providing companies the opportunity to potentially recoup the costs of research and development if they are given market control for the lifespan of their patent.[86]

However, extensive use of these patent controls also elicits criticism. Strict patent controls create drug monopolies that theoretically allow developers to raise prices indiscriminately as high as the market will allow.[87] These drug monopolies can have extremely detrimental effects on patient outcomes, as patients avoid taking medications or take smaller doses to save money on prescriptions.[88] Additionally, generic-drug companies were required to complete the same FFDCA process to gain approval as innovators, an expensive and time-consuming process.[89] Rather than using the trial results and research completed by originators, generic manufacturers were required to conduct the same tests and repeat research, despite utilizing equivalent ingredients which would virtually guarantee the same results. Many generic manufacturers were unable to shoulder the development costs involved in gaining approval through the FFDCA process or maintained prices close to the originator drug to afford the costs of FFDCA approval.[90] Because generic manufacturers were saddled with these costs and unable to significantly lower prices, consumers did not benefit fully from the presence of generics in the market.

In 1984, the Drug Price Competition and Patent Term Restoration Act, known as the Hatch–Waxman Act, was passed, with the goal of "expedit[ing] and streamlin[ing] both generic drug approvals and patent

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[84] Although there is some overlap, drug companies are typically divided into two categories, which will be referred to in this Note as originators and generic manufacturers. Originators invest in research and development and are rewarded with patent protection when they release a drug into the market. Generic manufacturers develop a bioequivalent, which is given access to the market through Hatch-Waxman protections. Daniel J. Gifford, *Government Policy towards Innovation in the United States, Canada, and the European Union as Manifested in Patent, Copyright, and Competition Laws,* 57 SMU L. REV. 1339, 1342 (2004).

[85] U.S. CONST. art. I, § 8, cl. 8.

[86] Ohly, *supra* note 83.

[87] *See* Werth, *supra* note 82.

[88] Tironi, *supra* note 16, at 321 ("More than 60 percent of the uninsured chronically ill, and 46 percent of the underinsured chronically ill report skipping medication due to cost.").

[89] Knocke, *supra* note 80.

[90] Allen M. Sokal, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, FINNEGAN (2010), *available at*http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=dfef53ed-54e4-491a-802a-01becb1f47bb.

litigation involving generic drugs."[91] One of the major provisions of the Hatch–Waxman Act is a new method of applying for drug approval for companies that manufacture bioequivalent generics. Instead of repeating the same cumbersome tests, generic manufacturers can now complete a shorter, less rigorous application which "piggybacks" the application filed by the innovator.[92] This allows generic manufacturers to save both time and money when entering the market, making the process smoother and benefitting both manufacturers and consumers.[93]

With the advent of the Hatch–Waxman Act, the generic market in the United States has grown.[94] However, the generic market under Hatch–Waxman depends heavily on price advantages to maintain market share. Because of this, the generic-market players in the United States might resist reference pricing, which lowers originator prices and lessens their price advantage in the market. Likely, generic manufacturers would join originators in lobbying against this regulation.

2. Medicare & Medicaid

Medicare is "a government health insurance program for individuals age sixty-five or older, certain disabled persons, and those with kidney failure who require dialysis (End-Stage Renal Disease, or ERSD)."[95] Because reimbursements from Medicare come from a government agency, Medicare allows for closer price control than the remaining majority of the U.S. pharmaceutical market.

Medicare covers "services and supplies considered medically necessary to treat a disease or condition."[96] Though each insurance agency defines "medically necessary" internally, Medicare defines it as "services or supplies that are needed to diagnose or treat [a] medical condition and that meet accepted standards of medical practice."[97] Medicare is divided into two sections for purposes of providing and reimbursing care and services.

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[91] Lisa Barons Pensabene & Dennis Gregory, *Hatch-Waxman Act: Overview*, PRACTICAL L. CO. (INTEL. PROP. & TECH.), *available at* http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Hatch-Waxman%20Act%20Overview%20lpensabene_dgregory.pdf; Kelly, *supra* note 18; Ohly, *supra* note 83.

[92] Ohly, *supra* note 83.

[93] *Id*.

[94] CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 27 (1998), *available at* http://www.cbo.gov/sites/default/files/pharm.pdf.

[95] Tironi, *supra* note 16, at 330.

[96] *What does Part A cover?*, MEDICARE, http://www.medicare.gov/what-medicare-covers/part-a/what-part-a-covers.html (last visited Sept. 17, 2014.).

[97] *What does Part B cover?*, MEDICARE, http://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html (last visited Sept. 17, 2014).

Medicare Part A includes hospital care, skilled nursing care, hospice, and other services.[98] Part A originally reimbursed pharmaceutical expenses directly as an itemized part of hospital costs. However, today Part A covers hospital expenses as a whole at a flat rate without separately charging for pharmaceuticals.[99] If hospitals are less able to account for fluctuating prices of drugs, they may have to swallow the costs of drugs which are priced higher than the reimbursement flat rate for the hospital stay as a whole.[100]

Medicare Part B, on the other hand, incorporates some of the principles of price control used in the European Union. Part B covers both medically necessary services and preventative services.[101] Medically necessary services include "services or supplies that are needed to diagnose or treat your medical condition and that meet accepted standards of medical practice."[102] This can include ambulance services, inpatient mental health services, and durable medical equipment. Preventative services is defined as "health care to prevent illness . . . or detect it at an early stage, when treatment is most likely to work best."[103]

Part B covers prescription drugs on a limited basis, such as drugs that are disbursed in the physician's office.[104] These reimbursements have, prior to 2004, been made based on the Average Wholesale Price (AWP). AWP is the "sticker price" listed by manufacturers in a national listing of pharmaceuticals.[105] Pharmaceuticals were reimbursed at either 95% of the AWP or the physician's billing rate. In 2004, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) changed the pricing model to 106% of the Average Sale Price (ASP), "defined by statute and based on reports of actual transactions."[106] The ASP pricing model mechanism allows Medicare to reimburse at lower rates than under the AWP.[107] Though ASP pricing is not externally influenced like reference pricing, it represents a level of price control that does not exist outside of Medicare.

Medicaid, another form of government-run health coverage, covers "some low-income people, families and children, pregnant women, the elderly, and people with disabilities."[108] Since Medicaid is run on a state-

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[98] *What does Part A cover?, supra* note 96.

[99] *Id.*

[100] Stanton, *supra* note 1.

[101] *What does Part B cover?, supra* note 97.

[102] *Id.*

[103] *Id.*

[104] Tironi, *supra* note 16, at 331.

[105] As Tironi notes, "It is not an actual average of prices paid by wholesalers." Tironi, *supra* note 16, at 331.

[106] *Id*.

[107] *Id*.

[108] *Medicaid & CHIP coverage,* HEALTHCARE.GOV, https://www.healthcare.gov/medicaid-

by-state basis, prescription drug coverage varies by state. However, many states utilize limits on prescription reimbursement, often based on AWP.

3. The Office of Veterans Affairs

The Veterans Health Care Act of 1992 established the 340B program, which "allows certain federally funded grantees and other safety net providers to purchase prescription drugs at reduced prices."[109] Under 340B, drug companies must sell to 340B entities at a reduced price, based on a "340B ceiling price" which "requires discounts of at least fifteen percent of the Average Manufacturer Price (AMP) for generics."[110] AMP (not to be confused with AWP) is calculated by a federally regulated formula:

> The manufacturer calculates pricing information for all of its covered outpatient drugs and sends this pricing data to HCFA within 30 days after the end of the quarter. HCFA will provide PHS with the data necessary for PHS to determine the ceiling price which will be used for resolving disputes, studies involving pricing data, auditing manufacturers, or other program purposes.[111]

The 340B program covers the following outpatient drugs: FDA-approved prescription drugs; over-the-counter (OTC) drugs written on a prescription; biological products that can be dispensed only by a prescription (other than vaccines); or FDA-approved insulin.[112]

B. Potential Effects of Reference Pricing on the Pharmaceutical Industry in the United States

Using international reference pricing would have widespread effects on the U.S. pharmaceutical industry. Some of these effects can be predicted by looking to other countries that use international reference pricing. However, the U.S. pharmaceutical industry is distinctive in its size and level of innovation. Because of this, the effects on the U.S. market could be different in terms of innovation, transformational care, black and grey

chip/getting-medicaid-chip/ (last visited Sept. 8, 2014).

[109] Tironi, *supra* note 16, at 334.

[110] *Id.*

[111] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing, 60 Fed. Reg. 51,488-89 (Oct. 2, 1995), *available at* http://www.hrsa.gov/opa/programrequirements/federalregisternotices/newdrugpricing100295.pdf.

[112] *Eligibility and Registration*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., http://www.hrsa.gov/opa/eligibilityandregistration/index.html (last visited Nov. 28, 2014).

markets, and patient provider relationships.

1. Innovation

Among developed nations, the United States pharmaceutical market is unique because of its comparative lack of government price controls. In particular, the United States features a free market for pharmaceuticals that is largely unregulated by government controls like reference pricing or price ceilings.[113] As such, pharmaceutical companies are able to charge prices in the United States that allow them to recoup a portion of the companies' research and development costs that often go unrecouped in other markets.[114] Patients in the United States pay more than consumers in other markets. For example, a 2003 study of thirty drugs found that U.S. consumers paid more for these drugs than consumers in the U.K. and France.[115]

"The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing nearly 20% of all domestic R&D funded by U.S. businesses."[116] According to the often-cited Tufts Center for the Study of Drug Development, U.S. pharmaceutical companies spend upwards of four billion dollars on research and development on a single drug.[117] GlaxoSmithKline, a major U.S. pharmaceutical company, spent $81,708 million on research and development from 1997 to 2011, and costs have only increased in recent years.[118] These expenses accumulate through clinical trials and filing patents, but more often, through drug failure—fewer than one-in-ten medicines that enter Phase 1 testing make it into the market.[119] These costs are often factored into the costs of drugs that actually enter the market, at least in the United States where pharmaceutical companies are able to price in research and development in a free market system.[120]

The main issue concerning price reform via government price regulation in the United States is whether reforms would have a negative

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[113] Tironi, *supra* note 16.

[114] *See* Salomeh Keyhani et al., *US Pharmaceutical Innovation in an International Context,* 100 AM. J. PUB. HEALTH 1075 (2010).

[115] Knocke, *supra* note 80, at 181.

[116] PHARMACEUTICAL RES. AND MFR. OF AM. (PHRMA), 2013 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE (2013), *available at* http://phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf.

[117] Matthew Herper, *The Truly Staggering Cost of Developing New Drugs*, FORBES (Feb. 10, 2012, 7:41 AM), http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/.

[118] *Id.*

[119] *Id.*

[120] *Id.*

impact on pharmaceutical innovation. Most companies within the pharmaceutical industry, as well as many outside of it, argue that price reform would dampen innovation.[121] The U.S. pharmaceutical market is a major source of profits for pharmaceutical companies, which allows these companies to cover losses in other countries. They may not be able to swallow the costs if the U.S. institutes price controls similar to other developed nations.

The United States is home to an astoundingly large proportion of pharmaceutical research and development. Six of the ten largest drug companies are based in the United States.[122] This is perhaps because pharmaceutical companies are allowed to set prices that let them recoup research and development costs.[123] Many argue that price setting in the United States, especially under a system of reference pricing intended to equalize prices between nations, would lead to a decrease in research and development.[124] This decrease would prevent potentially life-saving medications from eventually reaching not only the United States, but also the global market.[125] The U.S. government has pressured other countries to limit their price regulation, arguing that price regulations cause the United States to bear a disproportionate amount of research and development expenses in order to support "free-rider" countries.[126] The U.S. government has gone so far as to limit price negotiation in the 2003 Medicare Modernization Act.[127] Meanwhile, the pharmaceutical industry has similar objections. The Pharmaceutical Manufacturers Association of America has strongly opposed regulation and claimed that foreign governments are benefitting from U.S. innovation rather than paying their fair share of development costs.[128]

However, others argue that price setting in the United States would have a marginal (if any) effect on research and development overall.[129] A

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[121] Christopher R. Stambaugh, *State Price Control Laws Are the Wrong Prescription for the Problem of Unaffordable Drugs,* 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 897, 900 (2002).

[122] *Trade, Foreign Policy, Diplomacy, and Health: Pharmaceutical Industry*, WORLD HEALTH ORG., http://www.who.int/trade/glossary/story073/en/ (last visited Nov. 17, 2014).

[123] *See* U.S. DEP'T. OF COMMERCE, INT'L TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION (2004) (discussing how government controlled pricing reduces development in contrast to the United States. "As OECD countries individually seek to reduce spending on drugs through price controls, their collective actions reduce R&D that would provide substantial health benefits to all."), *available at* http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf. *Contra* Keyhani, *supra* note 114.

[124] Kraus, *supra* note 4; Stanton, *supra* note 1; Shah, *supra* note 79.

[125] Stambaugh, *supra* note 121.

[126] Keyhani, *supra* note 114, at 1075; Danzon, *supra* note 15.

[127] Keyhani, *supra* note 114, at 1075.

[128] *Id.* at 1075.

[129] *Id.* at 1077–78.

2010 study found the following:

> [The] United States is important but not disproportionate in its contribution to pharmaceutical innovation. Interestingly, some countries with direct price control, profit control, or reference drug pricing appeared to innovate proportionally more than their contribution to the global GDP or prescription drug spending.[130]

In other words, reference pricing is not directly correlated with a decrease in research and development. Others argue that while the United States may lead in pharmaceutical innovation, government and grant funding accounts for a large enough portion of this innovation to accommodate a decrease in private sector profits. Government funding has "played an indirect role—for example, by funding basic underlying research that is built on in the drug discovery process—in almost half of the drugs approved and in almost two-thirds of priority-review[131] drugs."[132]

2. Balancing Profit Margins with Transformational Care

Another issue that must be considered in applying reference pricing systems to the United States is balancing profit margins with the social goal of pharmaceutical innovation: transformational care. Transformational care is defined as "radical change introduced by visionary leaders at the level of the organization." This can take on many forms, but often includes openness to new treatments and new medications, which are difficult to introduce under traditional management models which value continuity.[133] The profitability of the pharmaceutical industry allows pharmaceutical companies to devote money to large-scale innovation.[134] These innovations include medicines that make large leaps in treatment and new therapies. Without the ability to recoup research and development costs, pharmaceutical companies may focus instead on cheaper incremental changes (this argument is similar to the argument often made that generic drugs limit innovation by discouraging originators, who see their profit

[130] *Id.* at 1078.

[131] Priority review drugs are drugs that, "if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications." When a drug is designated priority review, the FDA takes action on its approval within six months as opposed to the ten months expected under standard review. *Priority Review*, FDA (June 26, 2013), http://www.fda.gov/forpatients/approvals/fast/ucm405405.htm.

[132] Bhaven N. Sampat & Frank R. Lichtenberg, *What are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?* 30 HEALTH AFFAIRS 332, 332 (2011).

[133] Barbara Bigelow & Margaret Arndt, *Transformational Change in Health Care: Changing the Question*, 83 HOSPITAL TOPICS 19, 20 (2005).

[134] Stanton, *supra* note 1.

margins shrinking).[135] While important, these changes do not achieve the same level of transformational care that revolutionizes treatment.

3. Grey and Black Market Pharmaceuticals

One potential advantage to reference pricing in the United States is the decrease in parallel (grey) or black market imports.[136] Parallel markets develop when "a product covered by intellectual property rights in country A is exported and resold to country B without the right holder's authorization"; black markets involve the completely unregulated sale of drugs.[137] Websites, like the now defunct Silk Road (perhaps more known for its supply of illegal drugs than cheaper but legal pharmaceuticals) and many other online havens, allow access to lower priced medications in regulated markets like Canada.[138] Import of medications from Canada is a popular way to gain access to medicines that are prohibitively expensive in the United States.[139]

Reference pricing in the United States may lead to lower prices that more closely equal those of Canada and other regulated nations.[140] This may, in turn, lessen black or grey market importation. This theory, of course, supposes that reference groups in the United States and reference groups in countries like Canada, which are currently grey market importers, would be equivalent. If a drug is priced out of a reference group within the United States, black or grey market imports might continue or even increase.

While grey-market imports allow customers to save on prescription drugs, they also come with risks for the consumer and the pharmaceutical market. Consumers take a risk when ordering prescription drugs through the internet or other grey market means of receiving incorrect or potentially dangerous pills. Additionally, grey markets allow consumers to self-medicate without the expertise of a doctor to assure a correct diagnosis or a pharmacist to check dosages or interactions. Drugs without FDA approval are often obtainable through grey markets, and consumers may be unaware of damaging effects. Finally, like many Silk Road consumers who were located through their IP addresses during the government bust of the

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[135] *See generally* Beth Understahl, *Authorized Generics: Careful Balance Undone*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 355 (2005); Greger Vigen, *Health Care 2.0—Massive Implications of System Transformation*, HEALTH WATCH 10 (2013).

[136] Grey markets, a play on the traditional term "black market" used to refer to illegal sale of goods, is generally used as a synonym for parallel markets.

[137] Kraus, *supra* note 4, at 540.

[138] *Id.*

[139] Kraus, *supra* note 4.

[140] Stanton, *supra* note 1.

website, consumers of grey market pharmaceuticals may face legal action. Even if no conviction results, the costs of such legal action certainly would exceed the cost of the legal prescription.

Meanwhile, pharmaceutical developers suffer as well. Developers price their drugs for each country's market. If sales at a lower price trickle into another country, these pricing models are no longer effective, and developers cannot properly estimate their returns on costs.

C. Potential Effects on Patients and Providers

Reference pricing, if instituted in the United States, could have a large effect on the healthcare industry at the patient and provider level. The current free-market pharmaceutical pricing in the United States has both positive and negative effects on providers.

Pricing regulation may lead to pressure on physicians from pharmaceutical companies to prescribe their products through marketing.[141] In recent years, federal and state laws have restricted the use of marketing (and, through prosecution, attempted to discourage less open tactics like bribes) to persuade doctors to prescribe certain products. However, in the past, pharmaceutical companies have gone to extreme measures to get doctors to prescribe their products, from persuasive "perks" like trips and gifts to bribes.[142] These extreme measures may not have been limited to a few untoward companies. In 2004, when federal prosecutors began to crack down on bribery and illegal marketing, "[j]ust about every big global drug company — including Johnson & Johnson, Wyeth and Bristol-Myers Squibb — ha[d] disclosed in securities filings that it ha[d] received a federal subpoena, and most [were] juggling subpoenas stemming from several investigations."[143] Many of these cases led to sanctions for pharmaceutical companies, or laws designed to lessen these abuses. In recent years, this marketing has become smaller in scale, controlled by federal gift limits and state marketing limitations.[144]

Reference pricing might impact this smaller scale marketing, increasing it to levels that more closely mirror the actions the U.S. government attempted to cut down on in 2004. Pharmaceutical companies

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[141] Gardiner Harris, *MEDICAL MARKETING — Treatment by Incentive; As Doctor Writes Prescription, Drug Company Writes a Check*, N.Y. TIMES (June 27, 2004), http://www.nytimes.com/2004/06/27/us/medical-marketing-treatment-incentive-doctor-writes-prescription-drug-company.html?pagewanted=all&src=pm.

[142] *See generally* Novick v. Dep't of Health, Bd. of Med., 816 So. 2d. 1237, 1238 (Fla. Dist. Ct. App. 2002).

[143] Harris, *supra* note 141.

[144] For examples of state regulations, see *Marketing and Direct-to-Consumer Advertising of Pharmaceuticals*, NAT'L CONF. OF STATE LEGISLATURES (last updated Oct. 2013), http://www.ncsl.org/research/health/marketing-and-advertising-of-pharmaceuticals.aspx.

express fear of reference pricing affecting profit margins: "recent developments threaten to wrest control of pricing, pharmaceutical companies' single biggest determinant of profitability, further away from them."[145] With direct profits out of their hands, the pharmaceutical industry may react by pressuring doctors to endorse their products which fall outside the reference group and are not fully reimbursed by government or insurance payers, meaning patients would have to pay the difference out of pocket.

D. Interaction with the Affordable Care Act

The Affordable Care Act (ACA), a recent and highly contested piece of legislation passed by the Obama administration, attempts the difficult task of both reducing costs and increasing quality and accessibility of care within the United States. Many of these changes under the ACA will take place through changes in insurance coverage. Currently, the ACA does not address reference pricing as a cost saving mechanism for the healthcare industry. However, reference pricing might be an ideal way to achieve many of the goals of the ACA.

One of the major goals of the ACA is to extend coverage to all citizens.[146] Reference pricing would certainly make this goal more affordable for the government. Currently, one of the major criticisms of the ACA is the eventual cost of insuring the millions of uninsured through government-funded insurance. By balancing pharmaceutical costs and placing further regulations on what the government will pay for pharmaceuticals, reference pricing would lessen the gap between the federal budget and the cost of insuring every citizen under the ACA.[147]

Reference pricing would certainly assist in increasing coverage, but whether the decrease in costs would be sufficient to achieve the ACA's tandem goal of reducing costs is uncertain. Likewise, as discussed above, the ACA's final goal of improving care may be difficult to achieve as doctors battle with fewer options in prescribing.

V. CONCLUSION

In a globalized world, it is somewhat surprising that a system like reference pricing, utilized in every other developed nation and so entrenched in foreign pharmaceutical markets, is not used in the United

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[145] Pharmaletter, *supra* note 48.

[146] *Goal 1: Strengthen Health Care*, HHS.GOV, http://www.hhs.gov/secretary/about/goal1.html.

[147] John Cogan et al., *A Better Way to Reform Healthcare*, WALL ST. J. (Feb. 24 2010, 7:02 PM), http://online.wsj.com/news/articles/SB10001424052748704804204575069133264585068.

States. Certainly, there are downsides to reference pricing, most notably the potential harm to global research and development that would occur. However, the positive factors are substantial, such as a decrease in prices for consumers and government spenders. Overall, it seems that reference pricing in the United States may have a small negative effect on global markets, but an overall positive effect on consumers and providers in the United States, which far outweighs those factors.